

**AMENDMENTS TO THE CLAIMS**

1. (Withdrawn) A mucoadhesive composition for solubilization of insoluble drugs comprising 4~90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % by weight of at least one oil.

2. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, additionally comprising 0.01 ~ 90 % by weight of at least one emulsifier.

3. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, wherein said monoglyceride compound is chosen from a saturated or an unsaturated monoglyceride having 10 ~ 22 carbon atoms in the hydrocarbon chain.

4. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 3, wherein said monoglyceride compound is chosen from monoolein, monopalmitolein, monomyristolein, monoelaidin, monoerucin, mixture of monoglycerides semi-synthesized from triglycerides of vegetable or animal oil.

5. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, wherein said oil is chosen from triglyceride, iodized oil, vegetable oil and animal oil.

6. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 5, wherein said triglyceride is chosen from saturated and unsaturated triglyceride having 2 ~ 20 carbon atoms in each hydrocarbon chain.

7. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 6, wherein said triglyceride is chosen from triacetin, tributyrin, tricaproin, tricaprylin, tricaprins and triolein; wherein said iodized oil is chosen from Lipiodol, iodized poppy seed oil, Ethiodol and iodized soybean oil; wherein said vegetable oil is chosen from soybean oil, cottonseed oil, olive oil, poppy seed oil, linseed oil, sesame oil; and wherein said animal oil is chosen from squalane and squalene.

8-10. (Canceled)

11. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 2, wherein said emulsifier is chosen from a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and a bile acid.

12. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 11, wherein said phospholipid is chosen from a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative, and a polymeric lipid wherein a hydrophilic polymer is to conjugated to the lipid headgroup; wherein said non-ionic surfactant is chosen from a poloxamer (Pluronic:

polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij); wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative and sodium dodecyl sulfate (SDS); wherein said cationic surfactant is chosen from 1,2-dioleoyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleoyl-3-ethylphosphocholic acid (DOEPC) and  $3\beta$ -[N-[(N',N'-dimethylamino)ethan]carbonyl]cholesterol (DC-Chol); and wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

13-16. (Canceled)

17. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, additionally comprising 0.01 ~ 5 % by weight of another additive.

18. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 17, wherein the other additive is chosen from Cremophor, tocopherol, tocopherol acetate, fatty acids, fatty acid esters, fatty acid alcohols, alcohols and polyols.

19. (Withdrawn) The mucoadhesive composition for solubilization of insoluble drugs according to Claim 18, wherein the other additive is chosen from an alcohol chosen from

methanol, ethanol, propanol and isopropanol; and a polyol chosen from ethyleneglycol, propyleneglycol and polyethyleneglycol.

20. (Canceled)

21. (Withdrawn) A preparation method of mucoadhesive composition for solubilization of insoluble drugs according to Claim 1, wherein said method comprises the step of preparing a viscous liquid by solubilizing at least 4 ~ 90 % by weight of at least one monoglyceride compound in 0.01 ~ 90 % by weight of at least one oil.

22. (Withdrawn) The preparation method according to Claim 21, wherein the said mixture is heated to 50°C to speed up the solubilization process.

23. (Withdrawn) A preparation method of mucoadhesive composition for solubilization of insoluble drugs according to Claim 2, wherein said method comprises the step of preparing a viscous liquid by mixing at least 4 ~ 90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % by weight of at least one oil with 0.01 ~ 90 % by weight of at least one emulsifier.

24. (Withdrawn) The preparation method according to Claim 23 wherein the said mixture is heated to 50 °C to speed up the solubilization process.

25. (Withdrawn) The preparation method according to Claim 23 wherein the said mixture is sonicated in a bath type sonicator to speed up the solubilization process.

26. (Currently Amended) A mucoadhesive formulation for solubilization of insoluble drugs comprising ~~4 to 90 % by weight~~ 4 to 90 % by weight of at least one monoglyceride compound ~~monoolein, 0.01 to 90 % by weight~~ 0.01 to 90 % by weight of at least one oil selected from the group consisting of triacetin, tributyrin, tricaproin, tricaprylin, tricaprin, triolein, Lipiodol, iodized poppy seed oil, Ethiodol, iodized soybean oil, soybean oil, cottonseed oil, olive oil, poppy seed oil, linseed oil, sesame oil, squalane and squalene and ~~0.01 to 20 % by weight~~ 0.01 to 20 % by weight of at least one insoluble drug.

27. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, additionally containing ~~0.01 to 90 % by weight~~ 0.01 to 90 % by weight of at least one emulsifier.

28-34. (Canceled)

35. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said emulsifier is selected from the group consisting of a phospholipid, a non-ionic surfactant, an anionic surfactant, a cationic surfactant and a bile acid.

36. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 35,

wherein said phospholipid is chosen from a phosphatidylcholine (PC) and its derivative, a phosphatidylethanolamine (PE) and its derivative, a phosphatidylserine (PS) and its derivative and a polymeric lipid wherein a hydrophilic polymer is conjugated to the a lipid headgroup;

wherein said non-ionic surfactant is chosen from a poloxamer (Pluronic: polyoxyethylene-polyoxypropylene copolymer), a sorbitan ester (sorbitan esters; Span), a polyoxyethylene sorbitan (Tween) and a polyoxyethylene ether (Brij);

wherein said anionic surfactant is chosen from a phosphatidylserine (PS) and its derivative, a phosphatidic acid (PA) and its derivative ~~or~~ and sodium dodecyl sulfate (SDS);

wherein said cationic surfactant is chosen from 1,2-dioleoyl-3-trimethylammonium propane (DOTAP), dimethyldioctadecylammonium bromide (DDAB), N-[1-(1,2-dioleoyloxy)propyl]-N,N,N-trimethylammonium chloride (DOTMA), 1,2-dioleoyl-3-ethylphosphocholic acid (DOEPC) and  $3\beta$ -[N-[(N',N'-dimethylamino)ethan]carbonyl]cholesterol (DC-Chol); and

wherein said bile acid is chosen from cholic acid, its salt and derivatives; deoxycholic acid, its salt and derivatives; chenocholic acid, its salt and derivatives; and lithocholic acid, its salt and derivatives.

37 - 40. (Canceled)

41. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, wherein ~~said bioactive compound~~ the at least one insoluble drug is chosen from antivirals, steroidal anti-inflammatory drugs (SAID), non-steroidal anti-inflammatory drugs (NSAID), antibiotics, antifungals, vitamins, hormones, prostaglandins, prostacyclins, anticancer drugs, antimetabolitic drugs, miotics, cholinergics, adrenergic antagonists, anticonvulsants, antianxiety agents, major tranquilizers, antidepressants, anesthetics, analgesics, anabolic steroids, estrogens, progesterones, glycosaminoglycans, polynucleotides, immunosuppressants and immunostimulants.

42. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, additionally comprising ~~0.01 ~ 5 % by weight~~ 0.01 to 5 % by weight of another ~~additives~~ additive.

43. (Previously Presented) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 42, wherein the other additive is chosen from Cremophor, tocopherol, tocopherol acetate, fatty acids, fatty acid esters, fatty acid alcohols, alcohols and polyols.

44. (Previously Presented) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 43, wherein the additive is chosen from an alcohol chosen from methanol, ethanol, propanol and isopropanol; and a polyol chosen from ethyleneglycol and polyethyleneglycol.

45. (Canceled)

46. (Currently Amended) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, wherein the formulation is suitable for administration—~~route is chosen from~~ oral administration, buccal administration, mucosal administration, intranasal administration, intraperitoneal administration, subcutaneous injection, intramuscular injection, transdermal administration ~~[[and]]~~ or intratumoral injection.

47. (Previously Presented) The mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26 existing in liquid or semi-solid form.

48. (Withdrawn) A method of preparing the mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, wherein said method comprises the steps of:

1) solubilizing 4 ~ 90 % by weight of at least one monoglyceride compound in 0.01 ~ 90 % by weight of at least one oil (step 1); and

2) solubilizing completely 0.01 ~ 20 % by weight of at least one insoluble drug in said mixture in step (1) by stirring (step 2).

49. (Withdrawn) The preparation method according to Claim 48 wherein the said mixture is heated to 50 °C in step (1) to speed up the solubilization process.



50. (Withdrawn) The preparation method according to Claim 48 wherein the said mixture is sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

51. (Withdrawn) A preparation method of mucoadhesive formulation for solubilization of insoluble drugs according to Claim 26, wherein said method comprises the step of preparing a homogenous liquid by mixing completely at least one monoglyceride compound, at least one oil and insoluble drug.

52. (Withdrawn) The preparation method according to Claim 51 wherein the said mixture is heated to 50°C and sonicated in a bath type sonicator to speed up the solubilization process.

53. (Withdrawn) A method of preparing the mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said method comprises the steps of:

1) preparing a viscous liquid by mixing completely 4 ~ 90 % by weight of at least one monoglyceride compound, 0.01 ~ 90 % by weight of at least one oil and 0.01 ~ 90 % of at least one emulsifier (step 1); and

2) preparing a viscous liquid by mixing completely insoluble drug with said liquid in step (1) (step 2).

54. (Withdrawn) The preparation method according to Claim 53 wherein the said liquid is heated to 50 °C in step (1) to speed up the solubilization process.

55. (Withdrawn) The preparation method according to Claim 53 wherein the said liquid is heated to 50 °C in step (2) to speed up the solubilization process.

56. (Withdrawn) The preparation method according to Claim 53 wherein the said liquid is sonicated in a bath type sonicator in step (2) to speed up the solubilization process.

57. (Withdrawn) A method of preparing the mucoadhesive formulation for solubilization of insoluble drugs according to Claim 27, wherein said method comprises the steps of:

1) preparing oily liquid containing drug by solubilizing completely 0.01 ~ 20 % by weight of insoluble drug in 0.01 ~ 90 % by weight of at least one oil (step 1); and

2) preparing a homogeneous liquid by mixing completely said liquid in step (1) with 4 ~ 90 % by weight of at least one monoglyceride compound and 0.01 ~ 90 % of at least one emulsifier (step 2).

58. (Withdrawn) The preparation method according to Claim 57, wherein the said liquid is heated to 50 °C and sonicated in a bath type sonicator in step (2) to speed up the solubilization process.